REMARKS

Entry of the above amendments and reconsideration of this application are respectfully requested. Upon entry of the amendments, this application will contain claims 35-36, 38, 40-44, 46-49, and 51-54 pending and under consideration. For the reasons discussed below it is believed that all rejections presently of record have been overcome. Allowance of this application is therefore solicited.

Preliminarily, it is noted that the amendments to the claims introduce no new subject matter. The amendments in some cases reformat the independent claims or incorporate limitations already present in other claims. Other amendments to the claims are supported in the application as filed, for example, at page 23, line 25 (paclitaxel), page 34, lines 20-21 (angioplasty balloon), at page 9, lines 3-7 and Figs. 3-7 and descriptions thereof (coating within folds), and page 23, line 24 to page 25, line 25 (mixture of paclitaxel and other agents). Consideration and entry of the amendments is requested.

Also, an amendment to the specification is presented to delete "Background of the Invention" which occurred at page 6. This amendment introduces no new subject matter. The heading at this location was clearly a word processing error. The discussions involved clearly pertain to the invention, not background. Entry of this amendment is also requested.

Claim Rejections under 35 USC §102

Claims 35, 39, 40, 42, 45, 49, 52 and 53, as previously pending, stand rejected under 35 USC §102(b) over Roger et al., "Ceramide-coated Balloon Catheters Limit Neointimal Hyperplasia After Stretch Injury in Carotid Arteries". These rejections are respectfully traversed. Claims 39 and 45 have been cancelled, rendering this rejection moot as to those claims. Each of the remaining claims, as amended, requires paclitaxel in the coating on the balloon, and portions of the coating in folds of the balloon. The Roger et al. reference does not teach these features. Instead, the teachings of Roger et al. are limited to the use of ceramide, and the use of latex embolectomy balloons. Withdrawal of this rejection is solicited.

Claim Rejections under 35 USC §102 or Alternatively §103

Claims 36 and 43 stand rejected under 35 USC §102(b) as anticipated by or, alternatively under 35 USC §103(a) as obvious over Roger et al. These rejections are respectfully traversed. Claims 36 and 43, as amended, require paclitaxel in the coating on the balloon, and portions of the coating in folds of the balloon. As noted above, the Roger et al. reference does not teach these features. Withdrawal of this rejection is solicited.

Claim Rejections under 35 USC §103

Claims 37, 38, 41, 44, 46-48, 50 and 54 stand rejected under 35 USC §103(a) as being unpatentable over Roger et al. in view of Barry et al., US Patent No. 6,306,166, which teaches a controlled release system for paclitaxel in which the drug is incorporated within, and upon wetting within the body diffuses out of, a protective polymer layer. Claims 37 and 50 have been cancelled, rendering this rejection moot as to those claims. This rejection is respectfully traversed to the extent maintained against the remaining claims of this group.

Claims 38, 41, 44 and 46-48 as amended require a step of providing an angioplasty balloon with the features of: a dried layer containing paclitaxel on the outer surface of the balloon; portions of the dried layer in folds of the balloon; the balloon being free of a coating atop the dried layer; the balloon being free of a time-release layer; the balloon being free of a containment material; and, the balloon being free of a containment layer. At a minimum, this step is not obvious over Roger et al. in view of Barry et al., because it includes a combination of features not suggested by the references for the delivery of paclitaxel. Withdrawal of this rejection as applied to claims 38, 41, 44 and 46-48 is therefore requested.

Claim 54 as amended requires "providing a balloon catheter without a stent, the balloon catheter having a dried coating consisting of about 5 to about 500 micrograms of a single bioactive coating material consisting of paclitaxel per 25 mm^2 of the gross outer surface area of the balloon, the balloon catheter being free of any coating atop the paclitaxel, where the paclitaxel is not incorporated within a containment layer and amounts of the

paclitaxel are deliverable to the inner wall upon direct contact of the paclitaxel with the inner wall, and where the balloon has folds and amounts of the dried coating are positioned in folds of the balloon". Claim 54 further requires a step of "inflating the balloon at the treatment site to directly contact the paclitaxel in the coating with the interior wall of the blood vessel and thereby deliver paclitaxel to the interior wall without implanting a stent within the blood vessel". At a minimum, these steps are not obvious over Roger et al. in view of Barry et al., because they involve a combination of features not suggested by the references for the delivery of paclitaxel. Withdrawal of this rejection as applied to claim 54 is thus requested.

Claim 51 stands rejected under 35 USC §103(a) as being unpatentable over Roger et al. in view of Palasis et al., US Patent No. 6,369,039. This rejection is also respectfully traversed. Claim 51 as amended includes all of the features of claim 49. Claim 49 includes a step of "providing a balloon catheter including a balloon with a dried coating consisting of paclitaxel or a mixture of paclitaxel with another bioactive agent, the dried coating

being free of any additional coating atop the dried coating, where the paclitaxel or mixture of paclitaxel with another bioactive agent is not incorporated within a containment layer, and where the balloon has folds and portions of the dried coating are positioned in the folds". A step including this combination of features is not taught or suggested by Roger et al. in view of Palasis et al. Claim 51 is therefore patentably distinct over this combination of references, and withdrawal of the rejection is requested.

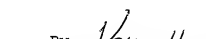
Conclusion

Certain claim amendments have been made in order to expedite the prosecution of this application, without admission to the propriety of the positions stated in the Office Action regarding the prior pending claims, and without prejudice of their further pursuit in this or a related application. It is submitted that the claim amendments clearly place the application in condition for allowance. Allowance of this application containing claims 35-36, 38, 40-44, 46-49, and 51-54 is thus solicited.

Request for Interview

If, for any reason, the Examiner is unable to allow the application as presently amended, request is hereby made for an in-person or telephonic interview prior to any further office action in the case. The undersigned attorney can be contacted to arrange the interview.

Respectfully submitted,

By 

Kenneth A. Gandy, Reg. No. 33386
Woodard, Emhardt, Moriarty, McNett
& Henry LLP
111 Monument Circle, Suite 3700
Indianapolis, Indiana 46204-5137
Tel.(317) 634-3456
Fax (317) 637-7561
Email: kgandy@uspatent.com